

REMARKS

1. Status of the claims

Claim 10 has been amended to incorporate the limitations of claim 20 and to incorporate language directed to the activity of the composition as recited in original claim 1. Claims 20 and 25-28 have been cancelled.

2. Claim Rejections Under 35 U.S.C. § 112, first paragraph

Amended Claim 10 is directed to a composition comprising one lyophilisate of dedifferentiated cells from *Crithmum maritimum*.

Applicants submit that the present application unambiguously demonstrates the in vivo cosmetic and therapeutic effects of the use of dedifferentiated *Crithmum maritimum* cells since Examples 1, 2 and 4 of the application teach an in vitro method of culturing dedifferentiated cells from a *Crithmum maritimum* tissue (see page 8), a method of preparing a lyophilisate from cultivated *Crithmum maritimum* cells (see page 10), and an experimental protocol for assessing the depigmenting effect of a cosmetic preparation containing a lyophilisate of dedifferentiated *Crithmum maritimum* cells (see page 13).

Following these teachings, Applicants consider that one skilled in the art would thus be able to practice the full scope of the claimed invention without undue experimentation. Reconsideration and withdrawal of the rejection are, therefore, requested.

3. Claim Rejections Under 35 U.S.C. § 103

3.1 Patentability of the Claims over Majmudar in View of Ennamany

Claims 10-18 and 20-28 have been rejected as being obvious over Majmudar in view of Ennamany. This rejection is respectfully traversed.

a) *Majmudar does not teach any compositions with any dedifferentiated cells.*

Majmudar discloses a composition for improving the skin's visual appearance comprising at least 1, 2 or 3 components selected from algae extracts, sea fennel, and Codium tomentosum extract (see [0010], lines 35-36). The compositions of Majmudar are in particular taught as being useful to treat "aged, mature, nutritionally-compromised or environmentally-damaged skin" (see [0009], lines 30-32).

However, Majmudar does not in any way teach or suggest the use of dedifferentiated plant cells, or a lyophilisate of dedifferentiated plant cells. On the contrary, the only example disclosed in Majmudar relates to a composition comprising codiavelane (butylenes glycol, water and Codium Tomentosum extract), Aosaine (hydrolysate of seaweed proteins of the algae Ulva lactuca), Monostroma (green flower algae), Chlorelline (Chlorella, an unicellular green algae) and Oleaphycol-CM which corresponds to a caprylic/Capric Triglyceride *Crithmum maritimum* extract, i.e. a derived product of *Crithmum maritimum* (see example 1, [0070] and the website of Presperse Incorporated, which distributes Olephycol-CM (http://www.presperse.com/Search_Next.asp?category_type=22&x=51&y=15®ion=NA&query=by_query)).

On the contrary, the present application provides a composition comprising a lyophilisate of dedifferentiated *Crithmum maritimum* cells, which unexpectedly induces skin depigmentation, through the inhibition of melanine synthesis in the reconstructed epidermis by blocking of

tyrosinase activity (see in particular example 4, pages 13 to 15 of the present application). The composition of the present invention is therefore useful for lightening black or asian skins, for example, or otherwise producing a depigmenting effect on the skin of any age. The unexpected depigmenting effect of the claimed composition results from the combined properties of halophyte plants, and more specifically of *Crithmum maritimum*, and of dedifferentiated cells since they “*maintain all cellular potentialities as the stem cells. They express all the genes of their genome, and therefore all the proteins which enable to each type of specialized cells to protect itself against the external environment*” (see the specification of the present application as filed, page 4, line 36 to page 5, line 4).

Majmudar fails to teach or suggest any composition having a depigmenting effect on the epidermis. Majmudar teaches compositions useful to renew the damaged layers of skin, such as the stratum corneum (see [0013, lines 23-25), and leading to an improved skin visual appearance (see [0025], lines 63-65). But, Majmudar explicitly indicates that obtaining a lightening effect of the skin would require the addition of “other beneficial agents and compounds such as (...) skin lightening agents (e.g. hydroquinone) (...)” (see [0059], lines 25-31). Therefore, whereas Majmudar discloses the use of *Crithmum maritimum* in a composition for improving the physical properties of the skin, it nevertheless fails to teach or even suggest the depigmenting properties of *Crithmum maritimum* (see [0033], lines 59-64: “*sea fennel contains ingredients that are anti-inflammatory and have a tightening effect on the skin. It can be used to strengthen muscle tone and increase the elasticity of the skin*”).

Applicants therefore submit that Majmudar fails to disclose or even to suggest a composition for depigmenting or lightening the epidermis comprising a lyophilisate of dedifferentiated cells from *Crithmum maritimum*. Claims 10-18 and 20-24 are thus neither anticipated nor obvious in view of Majmudar.

b) Ennamany does not teach any composition comprising cells from *Crithmum maritimum*

Ennamany discloses cosmetic compositions which are rich in metabolites produced by dedifferentiated plant cells, and comprising preferably at least one phytoalexin or a mix of phytoalexins (see page 1, lines 1-4, and page 19, lines 16-22). Phytoalexins are “any various antimicrobial chemical substances produced by plants to combat infection by a pathogen (as a fungus)” see <http://www.merriam-webster.com/dictionary/phytoalexin>). The homogenate of dedifferentiated cells incorporated in the Ennamany composition are used as an anti-oxidant agent, anti-free radical agent, soothing agent, or anti-irritating agent (paragraph [0110] of Ennamany).

Applicants therefore submit that the disclosure of Ennamany is far different from the present invention, wherein the dedifferentiated plant cells are from halophytic plant cells and more particularly from *Crithmum maritimum*. Indeed, as thoroughly disclosed in the specification of the present application, the depigmenting and lightening properties of halophytes plants derive from the mechanisms developed by halophytes for tolerating high salinity, rather than for combating infection by pathogens such as disclosed in Ennamany (see the specification at page 6, lines 17-23: “*In particular, the halophytes are seaside plants capable to stand a high salinity soil, humidity and wind. They are permanently fighting for maintaining the osmotic pressure in their cells, the water tending to cross the plasmic membrane towards the extracellular compartment with the higher sodium content*”).

Further, the teachings of Ennamany are restricted to a limited number of plant genera, not encompassing *Crithmum maritimum*. Ennamany explicitly provides a limitative list of the plant species which are to be selected for the preparation of the disclosed composition. Ennamany specifically states that: “*In the composition of the invention, the homogenate derives from the culture of dedifferentiated plant cells, elicited in an in vitro culture medium then dried, of the species *Salvia, Coleus, Rosmarinus, Gingko, Cannabis, Colchicum, Gloriosa, Asparagus,**

Arganier, Glycine, Medicago, Mungo, Erythrina, Oenothera, Papaver, Atropa, Datura, Solanum, Borago, Reseda, Amsonia, Catharantus, Pilocarpus, Digitalis, Coffea, Theobroma, Jasminum, Capsicum, Iris, Vigne, taxus, sequoia, chlorophytum, cacao, psoralea coryilfolia, vitex negundo, commiphora wighii, eucalyptus punctata, lavandula angustifolia, citrus limon, vanilla planifolia, marrubium vulgare, pilocarpus jaborandi, roses, betula, thé, and the cell mixes of such species". (See paragraph [0094] of Ennamany). Thus, not only does Ennamany fail to disclose the preparation of dedifferentiated cells from *Crithmum maritimum*, but it also fails to disclose the preparation of dedifferentiated cells originating from any plant of the same taxonomic order as *Crithmum maritimum*, namely from Apiales. The reference therefore clearly fails to teach the present invention.

c) No combination of Majmudar and Ennamany teaches the invention

First of all, Applicants submit that, even if one were to assume *arguendo* that Ennamany provides motivation to one of ordinary skill in the art to employ any of the plants cited in the reference, or, some cosmetically-valuable plant producing metabolites (e.g. phytoalexins) which are classified in the same taxonomic order of the above cited plants and possessing common characters of specialization with the above cited plants, Ennamany can not be considered to provide motivation for employing any plant from any taxonomic order of the Angiosperms, and specifically not for using *Crithmum maritimum*. Thus, even a combination of the references as suggested by the Examiner does not teach all of the limitations of Applicants' claims.

Applicants respectfully submit that it would not have been obvious to one skilled in the art at the time of the invention was made to prepare a lyophilisate of dedifferentiated cells of *Crithmum maritimum* for a therapeutic composition for depigmenting or lightening the skin. Indeed, none of the cited prior art documents actually suggest that *Crithmum maritimum* could be assimilated to a plant producing phytoalexins, and more specifically to any of the plant genera described in Ennamany. Applicants therefore respectfully submit that the teachings of Ennamany does not rescue the deficiencies of Majmudar, since the one skilled in the art would have had no

reasonable expectation of success in preparing a lyophilisate of dedifferentiated cells of *Crithmum maritimum* for a cosmetic or therapeutic composition for depigmenting or lightening the skin.

Applicants thus consider that Claims 10-18 and 20-24 are inventive over Majmudar in view of Ennamany. Reconsideration and withdrawal of the rejection are requested.

3.2 Patentability of the Claims over Majmudar in View of Mikimoto and Ennamany

Claims 10-18 and 20-24 have been rejected as being obvious over Mikimoto in view of Ennamany.

It is noted that claims 20 and 25-28 were not rejected over this combination of references. As noted above, claim 10 has been amended to incorporate the limitations of claim 20. This rejection has therefore, been obviated by the claim amendments. The rejection of claims 10-18 and 20-24 over Mikimoto in view of Ennamany should, therefore, be withdrawn.

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicants respectfully petition for a three (3) month extension of time for filing a reply in connection with the present application, and the required fee of \$1,110.00 is attached hereto.

If the Examiner has any questions concerning this application, the Examiner is requested to contact Leonard R. Svensson, Reg. No. 30,330 at the telephone number of (858) 792-8855. Facsimile communications may be sent to the undersigned at the facsimile number of (858) 792-3785.

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If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

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Respectfully submitted,

By 

Leonard R. Svensson

Registration No.: 30,330

BIRCH, STEWART, KOLASCH & BIRCH, LLP

12770 High Bluff Drive

Suite 260

San Diego, California 92130

(858) 792-8855

Attorney for Applicant